(6) The Director, the Deputy Director, and the Director, Office of Management and Communications, Center for Veterinary Medicine (CVM).

(7) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, and the Director and Deputy Director, Office of Management, Center for Drug Evaluation and Research (CDER).

(8) The Director, Office of Executive Operations, Office of the Senior Associate Commissioner, Office of the Commissioner and the Director, Office of Resource Management, ORA.

(9) Director, Office of Human Resources and Management Services, Office of Management and Systems, Office of the Commissioner.

(b) These officials may further redelegate this authority, with the limitation that the Director, Office of Human Resources and Management Services, OMS, OC, is delegated the authority to approve service fellowship plans and exceptions to the approved plans, and this official may not further redelegate this authority.

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives; and authority to perform due diligence determinations and informal hearings.

(a) The Deputy Commissioner is authorized to perform the due diligence determinations and informal hearings functions under section 156(d)(2)(B)(ii) of title 35 U.S.C. (35 U.S.C. 156), as amended, relative to patent term extensions.

(b) The Director, Center for Drug Evaluation and Research (CDER) and the Associate Director for Regulatory Policy, CDER, are authorized to perform the functions delegated to the Commissioner under title 35 U.S.C. 156, as amended, except for making due diligence determinations and holding of informal hearings under title 35 U.S.C. 156(d)(2)(B).

(c) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner, is authorized to perform the functions delegated to the Commissioner to make due diligence determinations under title 35 U.S.C. 156 (d)(2)(B), as amended, except for holding of informal hearings under title 35 U.S.C. 156(d)(2)(B)(ii).

(d) These officials may not further redelegate this authority.

§ 5.28 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335, 344(b), and 381(a)); section 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1455) (21 U.S.C. 145); section 9(b) of the Federal Caustic Poison Act (44 Stat. 1406; see also Public Law 86–613, section 19 formerly section 18); and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Director, Center for Food Safety and Applied Nutrition (CFSAN); and the Director of Regulations and Policy, CFSAN.

(2) The Director and Deputy Director, the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Directors for Science and for Regulations Policy, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the PHS Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing under the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of §16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Chief Mediator and Ombudsman, Office of the Ombudsman, Office of the Senior Associate Commissioner, Office of the Commissioner of Food and Drugs (Commissioner).

(2) The Director and Deputy Director, CFSAN.

(3) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER); the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER; the Associate Director for Regulatory Policy and the Associate Director for Medical Policy, CDER, the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors for Science and for Regulations Policy, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors, Office of Blood Research and Review, Office of Vaccines Research and Review, Office of Therapeutics Research and Review, and Office of Compliance and Biologics Quality, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

(d) These officials may not further redelegate this authority.

§ 5.29 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter for a stay of an effective date in §201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs:

(1)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2)(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter requesting in vitro test modifications under §331.29 of this chapter:

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, CDER.